

EXHIBIT 15

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PATENT

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE PATENT TRIAL AND APPEAL BOARD**

In Re:	Patent Application of Declan Walsh <i>et al.</i>	: Confirmation No.: 1099 : : Group Art Unit: 2876
Appln. No.:	15/262,818	: : Examiner: Daniel A. Hess
Filed:	September 12, 2016	: : Attorney Docket No.: 026723-02-5043-US15
For:	DOSE COUNTER FOR INHALER HAVING AN ANTI-REVERSE ROTATION ACTUATOR	: : :

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPELLANT'S BRIEF UNDER 37 C.F.R. § 41.37

This Brief is in furtherance of the Notice of Appeal filed January 19, 2018 in the above-identified patent application, which appeals from the Final Office Action dated July 19, 2017 (hereinafter "Office Action").

The Director is hereby authorized to charge any required fees, including any necessary fees under 37 C.F.R. §§ 1.17 and 41.20, or credit any overpayments in connection with this submission to Deposit Account No. **50-0310** (Billing No. 026723-02-5043-US15).

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

I. REAL PARTIES IN INTEREST

The real party in interest is TEVA PHARMACEUTICALS, INC., which is the parent corporation of the assignees of record, NORTON (WATERFORD) LIMITED, IVAX PHARMACEUTICALS IRELAND, and TEVA PHARMACEUTICALS IRELAND.

II. RELATED APPEALS AND INTERFERENCES

Appellant is not aware of any other appeals or interferences that will directly affect, or be directly affected by, or have a bearing on the Board's decision in this appeal.

III. SUMMARY OF CLAIMED SUBJECT MATTER

Claims 1-29 are pending. A copy of the claims is attached as an Appendix immediately following this Brief.

A summary of the rejected independent claim 1 follows, with reference to Appellant's Specification and Drawings as originally filed:

Claim 1:

Independent claim 1 is directed to a dose counter for an inhaler (*see, e.g.*, page 4, lines 6-7), the dose counter having a counter display (*see, e.g.*, FIG. 6C, tape 112) arranged to indicate dosage information (*see, e.g.*, page 4, lines 7-8; page 23, lines 11-14), a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input (*see, e.g.*, page 4, lines 8-10), wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements (*see, e.g.*, page 4, lines 10-12).

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

IV. ARGUMENT

A. The rejection of claims 1-13, 16, 17, and 20-29 under 35 U.S.C. § 103 over O'Leary is improper:

Claims 1-13, 16, 17, and 20-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication No. US 2002/0078950 (hereinafter "O'Leary").

Claim 1 of the present application recites:

A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, *wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.*

[emphasis added]

As described in the present specification, the regulator recited in claim 1 is highly advantageous, as it allows the counter display (e.g., tape) to advance so that doses are accurately counted, but also prevents the counter display from loosening if the inhaler is dropped onto a hard surface. Thus, the counter display is prevented from moving into a position that would provide an incorrect dose count (*see, e.g.*, page 33, line 19 to page 34, line 2 of the present specification). By regulating the counter display with incremental movements, instead of a constant application of force, the accuracy of the counter display is maintained without applying undesirably high friction against the counter display as it passes over other components of the dose counter (*see, e.g.*, page 34, lines 3-22 of the present specification). Thus, regulating the motion of the counter display with incremental movements achieves at least two objectives: it prevents undesirable movement of the counter display if the inhaler is dropped, and avoids the use of high friction against the counter display.

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

By way of example, according to an embodiment illustrated by FIGS. 6D, 6F, and 15 of the present application, reproduced below, the regulator may be formed by the inner engagement surface 300 of a bobbin 110, which has concavities that engage incrementally with control elements 128, 130 disposed on the forks 124, 126 of a shaft upon which the bobbin is rotatably mounted.

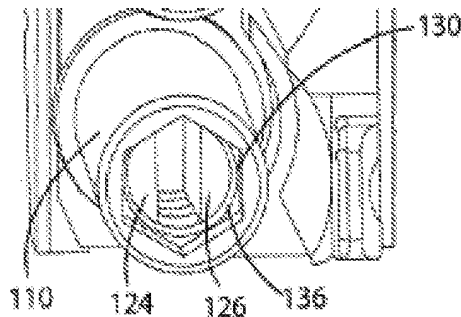


FIG. 6D of the present application

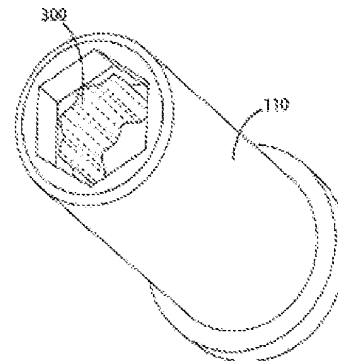


FIG. 6F of the present application

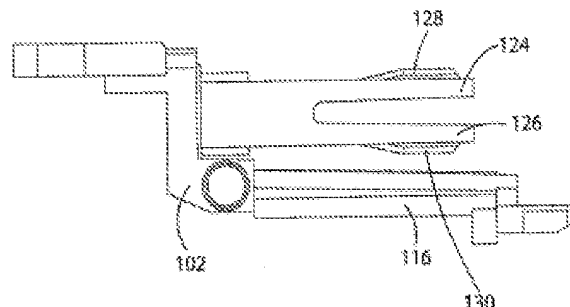


FIG. 15 of the present application

In rejecting claims under 35 U.S.C. § 103, it is incumbent upon the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See, In re Fine*, 837 F.2d 1071, 1073, (Fed. Cir. 1988). In so doing, the Examiner must make the factual determinations set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). “[T]he examiner bears the initial burden, on review of the prior art or on any other ground, of presenting a *prima facie* case of unpatentability.” *In re Oetiker*, 977 F.2d 1443, 1445 (Fed. Cir. 1992). Furthermore, “there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed.

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

Cir. 2006)). Moreover, “[a] factfinder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of argument reliant upon ex post reasoning.” *Id.* at 421.

Appellant respectfully submits that the Examiner’s findings with respect to the scope and content of O’Leary have no factual basis; and that the erroneous factual findings are a result of impermissible hindsight. Therefore, the Office has not met its burden and a *prima facie* case of obviousness has not been established.

1. *O’Leary does not teach, suggest or disclose a regulator that regulates motion of the counter display with incremental movements.*

O’Leary discloses a dose counter for an inhaler with a ribbon 128 having successive numbers printed thereon, a rotatable bobbin 132, and an indexing spool 134 rotatable in a single direction, wherein the ribbon 128 unrolls from the bobbin 132 so that the numbers are successively displayed as the spool 134 is rotated or advanced, as shown in Fig. 15 of O’Leary, reproduced below. *See* O’Leary ¶ [0054].

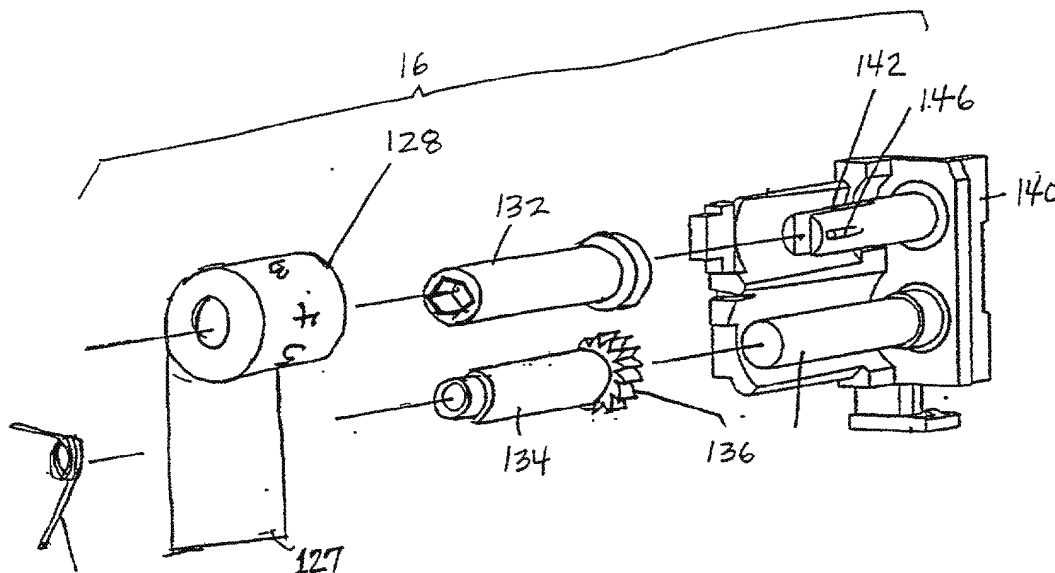


Fig. 15 of O’Leary

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

Additionally, O'Leary describes a bobbin 132 which is rotatably mounted on the bobbin shaft 142. O'Leary states that "[t]he bobbin shaft is preferably forked and includes radial nubs 146 for creating a *[i.e. singular]* resilient resistance to rotation of the bobbin 132 on the shaft". O'Leary ¶ [0057]. *This is the only disclosure provided by O'Leary that relates to resisting the motion of the counter display. O'Leary does not disclose or suggest a regulator that uses incremental movements to regulate the movement of a counter display, and provides no reason for a skilled artisan to employ such incremental movements.*

The Examiner acknowledges that "O'Leary does not show what is inside the bobbin 132 beyond the hexagonal part." Office Action page 5. Instead, the Examiner states that features of independent claim 1 ***could be*** met by O'Leary "***if*** there are some kind of complementary features inside of the bobbin 132 that match the nubs 146 of the shaft 142." *Id.* (emphasis added). The Examiner then concludes that "[n]evertheless, it is reasonable to expect that there would be some kind of complementary features to match the nubs 146 because connecting parts are typically complementary...the nubs 146 should be interacting with something complementary inside of 132, otherwise the nubs aren't interacting with anything." *Id.* at pages 5-6. The Examiner further states, "If the corresponding inner surface of O'Leary were smooth, then the nubs would not 'create a resilient resistance to rotation' as O'Leary requires. In order to 'create a resilient resistance to rotation' as O'Leary states that there is, the nubs should slip into corresponding concavities." *Id.* at page 6.

The Examiner has erred for several reasons. First, the Examiner has misconstrued the scope and content of the prior art in stating that there should be complementary features to match O'Leary's nubs because "connecting parts are typically complementary" and the nubs are non-functional without such complementary features. This interpretation of O'Leary is unfounded, as the nubs taught by O'Leary are not intended to "connect" to anything, as the Examiner asserts. O'Leary clearly states that the purpose of the nubs is to create a resilient resistance to rotation of the bobbin on the shaft, *i.e.*, the protruding nubs provide added friction as they are urged against the bobbin. There are no teachings in O'Leary that suggest the nubs are supposed to function as "connecting parts" or to complement another feature, as stated by the Examiner. Indeed, O'Leary states that it is the radial nubs 146 that create the resilient resistance to rotation. O'Leary discloses

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

no other structure as cooperating with the nubs, as the Examiner suggests. For at least that reason, a skilled artisan may interpret O'Leary as describing a device wherein the radial nubs engage a smooth inner shaft of the bobbin to provide continuous resistance force as the bobbin rotates, in order to prevent free spooling of the bobbin. The Examiner's rejection of this interpretation based on a finding, without evidence, that a smooth inner surface could not "create a resilient resistance to rotation" is misplaced. The type of "resilient resistance" described by O'Leary is commonly applied in numerous contexts; for example, common brake pads on a bicycle wheel provide resilient resistance against a smooth wheel rim, thereby slowing the rotation of the wheel. There is absolutely no requirement for corresponding concavities to achieve the type of resilient resistance described by O'Leary. Thus, the Examiner has misconstrued the scope and content of O'Leary by making unfounded factual findings.

Second, even if it were possible to modify the subject matter disclosed in O'Leary to arrive at the claimed invention, the mere possibility of doing so does not make the claimed invention obvious in view of O'Leary. That is especially true where, as here, there is no articulated rationale to modify O'Leary to arrive at the claimed invention. There must be a reason to modify a reference in the specific manner as claimed, but O'Leary provides no reason to modify a dose counter so that it regulates the counter display with incremental movements. As stated in the present specification, the incremental movements provided by the claimed invention solve the problem of dose miscounting due to an accidental advance of the dose counter if an inhaler is dropped, and without the application of constant friction against the counter display. These objectives are not stated or suggested by O'Leary. *In fact, the claimed invention solves a problem presented by the arrangement taught by O'Leary, in which the protruding nubs provide constant friction against the bobbin.* O'Leary does not acknowledge or suggest that there is a problem – this is simply the arrangement taught by O'Leary, whereby protruding nubs create a resilient resistance to the bobbin in a manner that is commonly used to slow down rotation. O'Leary provides no suggestion whatsoever that a modification to this arrangement would be desirable. The problem to be solved must be gleaned from the prior art, not from an applicant's specification, and O'Leary is silent with regard to any of the problems solved by the claimed invention.

Application No. 15/262,818

Attorney Docket No. 026723-02-5043-US15

Appellant's Brief

The Examiner has made an erroneous factual finding, seemingly as a result of impermissible hindsight. Unsupported speculation as to the significance and functionality of a prior art disclosure, or how that prior art might be modified, does not satisfy the Office's burden of articulating a reasoned basis for a determination of *prime facie* obviousness. The key requirement of *prima facie* obviousness under 35 U.S.C. § 103(a) is a clear articulation of a reason with a *rational* underpinning to support the legal conclusion of obviousness. M.P.E.P. § 2141. The reason offered in support of the present rejection is based on a factual error with respect to the teachings of O'Leary and therefore lacks a rational underpinning. For at least the foregoing reasons, O'Leary fails to render obvious independent claim 1. Accordingly, the rejection of independent claim 1 as well as dependent claims 2-13, 16, 17, and 20-29 under 35 U.S.C. § 103(a) is considered improper. If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. M.P.E.P. § 2143.03 citing *In re Fine*, 837 F.2d 1071 (Fed. Cir. 1988).

Appellant notes that claims 14-15 and 18-19 were deemed allowable by the Examiner, but declined to rewrite the claims into independent form in view of the arguments presented above.

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

Conclusion:

For at least the foregoing reasons, Appellant submits that the rejections of claims 1-13, 16, 17, and 20-29 set forth in the Final Office Action were made in error and should therefore be reversed.

Respectfully submitted,

Date: May 21, 2018

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Application No. 15/262,818

Attorney Docket No. 026723-02-5043-US15

Appellant's Brief

V. CLAIMS APPENDIX

1. A dose counter for an inhaler, the dose counter having a counter display arranged to indicate dosage information, a drive system arranged to move the counter display incrementally in a first direction from a first station to a second station in response to actuation input, wherein a regulator is provided which is arranged to act upon the counter display at the first station to regulate motion of the counter display at the first station to incremental movements.
2. The dose counter as claimed in claim 1 in which the counter display comprises a tape.
3. The dose counter as claimed in claim 2 in which the tape has dose counter indicia displayed thereon.
4. The dose counter as claimed in claim 2 wherein the first station comprises a first shaft, the tape being arranged on the first shaft and to unwind therefrom upon movement of the counter display.
5. The dose counter as claimed in claim 4 in which the first shaft is mounted for rotation relative to a substantially rotationally fixed element of the dose counter.
6. The dose counter as claimed in claim 5 in which the regulator comprises at least one projection on one of the first shaft and the substantially rotationally fixed element, which is arranged to engage incrementally with one or more formations on the other of the substantially rotationally fixed element and the first shaft.
7. The dose counter as claimed in claim 6 in which at least two said projections are provided.
8. The dose counter as claimed in claim 6 in which exactly two said projections are provided.
9. The dose counter as claimed in claim 6 in which each projection comprises a radiused surface.

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

10. The dose counter as claimed in claim 6 in which the at least one projection is located on the substantially rotationally fixed element which comprises a fixed shaft which is fixed to the main body of the dose counter, the first shaft being rotationally mounted to the fixed shaft.

11. The dose counter as claimed in claim 10 in which the fixed shaft has at least two flexible legs, and each leg has at least one said projection formed in an outwardly facing direction thereon, said one or more formations being formed on an inwardly facing engagement surface of the first shaft, said at least one projection being arranged to resiliently engage said one or more formations.

12. The dose counter as claimed in claim 6 in which a series of said formations are provided.

13. The dose counter as claimed in claim 6 in which an even number of said formations is provided.

14. The dose counter as claimed in claim 6 in which from eight to twelve of said formations are provided.

15. The dose counter as claimed in claim 14 in which ten of said formations are provided.

16. The dose counter as claimed in claim 6 in which each said formation comprises a concavity formed on an engagement surface.

17. The dose counter as claimed in claim 16 in which each concavity comprises a radiused surface wall portion which merges on at least one side thereof into a flat wall portion surface.

18. The dose counter as claimed in claim 17 in which the engagement surface includes a series of said concavities and in which convex wall portions of the engagement surface are formed between each adjacent two said concavities, each said convex wall portion comprising a convex radiused wall portion.

Application No. 15/262,818

Attorney Docket No. 026723-02-5043-US15

Appellant's Brief

19. The dose counter as claimed in claim 18 in which each convex radiused wall portion of each convex wall portion is connected by said flat wall portion surfaces to each concavity which is adjacent thereto.

20. The dose counter as claimed in claim 10 in which the fixed shaft comprises a split pin with fork legs and in which each projection is located on a said fork leg.

21. The dose counter as claimed in claim 4 in which the first shaft comprises a substantially hollow bobbin.

22. The dose counter as claimed in claim 21 in which said one or more formations are located on an inner surface of the bobbin.

23. The dose counter as claimed in claim 4 wherein the drive system comprises a tooth ratchet wheel arranged to act upon a second shaft which is located at the second station, the second shaft being rotatable to wind the tape onto the second shaft.

24. The dose counter as claimed in claim 23 in which the second shaft is located on the main body of the dose counter spaced from and parallel to the first shaft.

25. The dose counter as claimed in claim 23 in which the tooth ratchet wheel is fixed to the second shaft and is arranged to rotate therewith.

26. The dose counter as claimed in claim 23 which includes an anti-back drive system which is arranged to restrict motion of the second shaft in a tape winding direction.

27. The dose counter as claimed in claim 1 in which the regulator provides a resistance force of greater than 0.1 N against movement of the counter display.

28. The dose counter as claimed in claim 27 in which the resistance force is greater than 0.3 N.

Application No. 15/262,818
Attorney Docket No. 026723-02-5043-US15
Appellant's Brief

29. The dose counter as claimed in claim 27 in which the resistance force is from 0.3 to 0.4 N.